Proposed
Pharmaco-Diagnostics (Rx-Dx) Partnerships Program

Presentation to ATP Advisory Committee Meeting

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Personalized Medicine: *The Engine of 21st Century Economic Growth*

- **Hundreds of billions of healthcare dollars are wasted each year prescribing therapies that do not help—and sometimes harm--individual patients.**
- **U.S. pharmaceutical and biotech companies loose tens of billions of dollars annually in the 80% of drugs that fail clinical trials.**

FDA Pharmacogenomic Guidelines

If a diagnostic is used for "choosing or dosing of drugs" in a clinical trial the FDA recommends that diagnostic approval be obtained in conjunction with drug approval to "provide simpler and more consolidated trials."

October 29, 2003 Draft Guidelines page 6

FDA "Critical Path" Report

"The emerging techniques of pharmacogenomics and proteomics show great promise for contributing biomarkers to target responders, monitor clinical response, and serve as biomarkers of drug effectiveness." However, according to the report, "much development work" must occur before these diagnostic techniques can be easily and widely used.

MERCK ONCE DAILY VIOXX (rofecoxib)

- Launched in 1999 and approved in 80 countries to treat arthritis and acute pain
- Taken by over 80 million people over 3 years; $2.5 billion in sales in 2003
- Voluntarily withdrawn by Merck on September 30 due to increased heart attack and stroke risk: 1.5% Vioxx users vs. 0.75% in control group
- $ billions in lawsuit settlements anticipated.

MERCK ONCE DAILY VIOXX (rofecoxib)

"[W]hat if Merck had developed a diagnostic assay that could be used to identify those at risk individuals? Then they could have been excluded from the trials. And practicing physicians could use a similar test to screen their patients, only prescribing the drug to those for whom it could provide a benefit. Of course, hindsight is 20/20."

Biomarkers: The Pendulum Finally Swings
By Jennifer VanBrunt, Editor, Signals Magazine
October 20, 2004 www.signalsmag.com

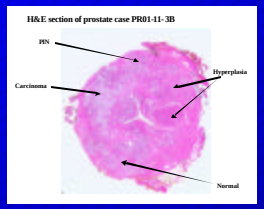
Diagnostic Development: *The Rate Limiting Step*

"The rate-limiting step [in co-development of diagnostics with drugs] is the industry's ability to develop meaningful diagnostics. Therapies have outpaced diagnostics."

Dr. Susan Desmond-Hellmann, President, Product Development, Genentech.

quoted in *Signals* (www.signalsmag.com) July, 2004

21st Century Drugs are Prescribed Using 19th Century Diagnostics



"Tumors are still classified—and the type and course of therapy determined—using antiquated pathological classification systems despite clear evidence that the biochemical and genetic characteristics of tumors, not their physical appearance, determine whether a given therapy will be successful."

Dr. David Parkinson, VP of Oncology, Amgen. NCI Roundtable, Jan. 2004

Why Not Rely on VC Funding?

BusinessWeek June 3, 2004

Biotech's Tough New Taskmasters

…A close look at some of the recent deals suggests that VCs are applying the harsh lessons they learned from the hundreds of biotech investments that went sour over the past few years. **No longer will they throw money at** grandiose promises about potential genomics discoveries or **new technology platforms**. These days, VCs are demanding blockbuster [drugs] that are likely to hit the market in the next couple of years.

Pharmaco-Diagnostics Partnerships (Rx-Dx)

Goal: Provide tangible incentives to pharmaceutical and diagnostics companies to support the development of diagnostics technologies and markers to better predict and monitor response to drugs.

Business Model: Provide (i) federal matching funds to joint ventures between pharmaceutical and diagnostic companies and (ii) regulatory and exclusivity incentives to drugs and devices jointly approved under this program.

Rx/Dx Program Structure

- **Federal matching funds (50:50) for joint ventures between pharmaceutical and diagnostic companies leading to companion diagnostics (NIST-ATP) (up to $5 million)**
- **Single company awards for high-risk diagnostic platform development (NIST-ATP) (up to $2 million)**
- **Provide non-patent exclusivity benefits of Orphan Drug Act to drug and companion diagnostic. (FDA)**
- **Provide fast-track dual review of drug and diagnostic (FDA)**

Why ATP?

ATP ADVANCED TECHNOLOGY PROGRAM

• Need to accelerate the development and application of broad, enabling platform technologies across several technical disciplines (materials, software, life science

• Experience in promoting and facilitating Joint Ventures of the type that can be models for RX/Dx partnerships

• Compelling economic and commercial rationale for companion diagnostics

Rx-Dx Exclusivity Model

FDA Orphan Products Development Program

http://www.fda.gov/orphan

- Approved drugs designated as "orphan" drugs for rare diseases or conditions (affects less than 200,000 persons in the U.S.) entitled to seven years of regulatory exclusivity for that disease or condition.

- Extend to drugs for larger diseases if subset of responders using companion Dx below 200,000.

Further Information:

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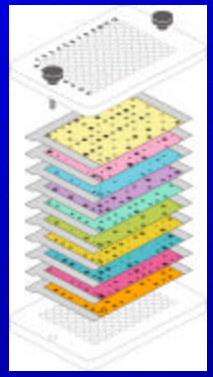
*The views and ideas herein are those of Mr. Cohen and do not necessarily represent those of 20/20 GeneSystems, Inc. or its shareholders.



20/20's Layered Protein Array